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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,412

09/18/2006

Hyesook Kim

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7590

08/27/2009

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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,412	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> AMBER D. STEELE	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/8/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-30 were originally filed on September 18, 2006.

The preliminary amendment received on September 18, 2006 amended claims 1, 6, 8, 11, 12, and 15.

Claims 1-30 are currently pending.

Claims 1-11 are currently under consideration.

### ***Election/Restrictions***

2. Applicant's election of Group I (claims 1-11) in the reply filed on May 29, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 12-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on May 29, 2009.

4. Applicants also elected species of polyclonal and drug metabolizing enzyme. However, it is noted that a species requirement was not made in the restriction mailed on April 30, 2008.

***Priority***

5. The present application claims status as a 371 (National Stage) application of PCT/US05/08973 filed March 18, 2005 which claims the benefit of U.S. Provisional application 60/554,538 filed March 19, 2004.

***Information Disclosure Statement***

6. The information disclosure statement (IDS) submitted on January 8, 2007 is being considered by the examiner.

***Specification***

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Invention as Claimed***

8. Independent claim 1: An antibody microarray screen comprising a substrate, polyclonal antibodies that are purified immunoglobulins wherein said antibodies are spotted on predetermined positions on said substrate and fluids processed for immunoglobulin isolation wherein said unprocessed fluids with higher amounts of proteins than said purified immunoglobulin proteins to compensate nonimmunoglobulin proteins in said unprocessed fluids are spotted on said predetermined positions on said substrate and variations thereof.

Independent claim 8: An antibody microarray screen comprising a substrate, polyclonal antibodies as purified immunoglobulins wherein said antibodies are spotted on predetermined positions on said substrate and anti-sera with higher amounts of proteins than said purified

Art Unit: 1639

immunoglobulin proteins to compensate nonimmunoglobulin proteins in said unprocessed fluids are spotted on said predetermined positions on said substrate and variations thereof.

*Claim Objections*

9. Claims 1-7 are objected to because of the following informalities: the claims contain subject matter that is drawn to a nonelected invention (i.e. monoclonal antibodies, see line 2 of independent claim 1). Appropriate correction is required.

10. Claims 1-7 are objected to because of the following informalities: independent claim 1 reads “fluids unprocessed for immunoglobulin isolation”. Alternative claim language is suggested as follows: “unprocessed fluids for immunoglobulin isolation”, “fluids that are unprocessed for immunoglobulin isolation”, “unprocessed fluids wherein immunoglobulins have not been isolated”, etc. Appropriate correction is required.

11. Claims 1-7 are objected to because of the following informalities: independent claim 1 reads “polyclonal antibodies that are purified immunoglobulins...said purified immunoglobulins proteins”. Alternative claim language is suggested: “purified polyclonal antibodies...said purified polyclonal antibodies”. Appropriate correction is required.

12. Claims 8-12 are objected to because of the following informalities: independent claim 8 reads “polyclonal antibodies as purified immunoglobulins...said purified immunoglobulin proteins”. Alternative claim language is suggested: “purified polyclonal antibodies...said purified polyclonal antibodies”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, the preambles of independent claims 1 and 8 refer to “an antibody microarray screen”. However, the body of the claim describes a product (e.g. comprising a substrate, polyclonal antibodies, and fluids unprocessed or anti-sera) and a method of making (e.g. spotted on predetermined positions). Therefore, it is not clear if the invention as claimed is drawn to a product, a method of screening, or a method of making. Due to the indefinite nature of the claims, it is not clear what is included or excluded from the claim.

15. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A nexus is missing between the preamble and the last line of the claim.

16. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. There are no positive method steps in the present claims (e.g. spotting is part of a wherein clause only).

17. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining which unprocessed fluids or anti-sera have higher amounts (please note: this is only required if the spotting is an actual method step in the claim or if the determination is part of a screening method). In addition, would the determination then render the fluids processed?

18. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, independent claim 1 reads “antibodies are spotted on predetermined positions on said substrate...said unprocessed fluids...are spotted on said predetermined positions on said substrate”. It is not clear if both the polyclonal antibodies and the unprocessed fluids are spotted on the same or different predetermined positions on said substrate. If the same predetermined positions are required, is a specific structure necessary (e.g. antibodies spotted first then unprocessed fluids, etc.)? However, it is noted that this would then result in the unprocessed fluids to be spotted on the antibodies and not actually on the substrate.

19. Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the

Art Unit: 1639

presently claimed invention. The presently claimed inventions of independent claims 1 and 8 are drawn to “an antibody microarray screen”. However, dependent claims 6 and 11 appear to be drawn to a method of determining optimal spotting concentrations of IgG. Therefore, it is not clear how this method relates to the antibody microarray screen.

#### ***Search Precluded***

20. A search of the present claims was precluded because it is not clear what invention is actually being claimed. After the claims are amended to clarify the presently claimed invention, a search of the prior art will be performed. However, it is noted that a secondary restriction may be required after clarification of the claimed inventions. In addition, an inventor and assignee search regarding double patenting was not performed because it is not clear which inventions would read on the present claims.

#### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Primary Examiner, Art Unit 1639

August 21, 2009